



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,440	06/20/2005	Elisabeth Bock	BOCK8	6815
1444 7590 09/13/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER LI, RUIXIANG	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 09/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,440

Applicant(s)

BOCK ET AL.

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 5, 8-15, 17, 18, 20, 25-43, 45, 46, 48, 49 and 55-57 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1, 4, 5, 8-15, 17, 18, 20, 25-43, 45, 46, 48, 49, and 55-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1, 4, 5, 8-15, 17, 18, and 20, drawn to a method of modulating the interaction between a fibroblast growth factor receptor and a polypeptide having a binding site to said receptor.
- II. Claims 25-42, drawn to a screening method for a compound capable of modulating interaction between a fibroblast growth factor receptor and a polypeptide having a binding site to said receptor.
- III. Claim 43, drawn to a method for molecular design for a compound capable of modulating the interaction between a fibroblast growth factor receptor and a polypeptide having a binding site to said receptor.
- IV. Claims 45 and 46, drawn to a peptide fragment and a compound comprising at least one peptide fragment.
- V. Claims 48 and 49, drawn to an antibody capable of binding to an epitope comprising at least one of the sequences set forth in SEQ ID NOS: 1-146.
- VI. Claims 55, drawn to a method for treating an individual in need, comprising using

a peptide fragment.

VII. Claim 56, drawn to a method for treating an individual in need, comprising using an antibody.

VIII. Claim 57, drawn to a method for determining in a sample the presence of a substance comprising an epitope comprising at least one of the sequences set forth in SEQ ID NOS: 1-146.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is considered to be a method of modulating the interaction between a fibroblast growth factor receptor and a polypeptide having a binding site to said receptor.

The special technical feature of Group II is considered to be a screening method for a compound capable of modulating interaction between a fibroblast growth factor receptor and a polypeptide having a binding site to said receptor.

The special technical feature of Group III is considered to be a method for molecular design for a compound capable of modulating the interaction between a fibroblast growth factor receptor and a polypeptide having a binding site to said receptor.

The special technical feature of Group IV is considered to be a peptide fragment and a compound comprising at least one peptide fragment.

The special technical feature of Group V is considered to be an antibody

capable of binding to an epitope comprising at least one of the sequences set forth in SEQ ID NOS: 1-146.

The special technical feature of Group VI is considered to be a method for treating an individual in need, comprising using a peptide fragment.

The special technical feature of Group VII is considered to be a method for treating an individual in need, comprising using an antibody.

The special technical feature of Group VIII is considered to be a method for determining in a sample the presence of a substance comprising an epitope comprising at least one of the sequences set forth in SEQ ID NOS: 1-146.

Accordingly, Groups I-VIII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Thus, unity of invention is lacking and restriction is appropriate.

3. Furthermore, the application contains claims that use the Markush language, reciting a group of fibroblast growth factor receptors (see, e.g., claim 4) and numerous peptides (see, e.g., claims 1, 8-12, 27, 45). The *In re Harnisch* test for unity of invention is applied in the Markush practice. In the instant case, since the recited fibroblast growth factor receptors and peptides do not appear to have a substantial structure similarity as a whole, restriction to a single sequence is required.

Applicant is advised that a reply to this requirement must include an identification of a single fibroblast growth factor receptor and/or a single peptide (represented by a SEQ ID NO) that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. **The Examiner notes that this is not a species election requirement; rather it sets forth additional invention groups.**

Species Election

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: various diseases as recited in claims 29-38.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: according to PCT rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of the PCT administrative Instructions, all alternatives of a Markush Group must have a common property or activity. The species listed above are not regarded as being of similar nature because the species do not appear to share a pathological feature.

Applicants are further required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a

listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP. § 809.02 (a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (I).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Applicant is advised that the final rules on claims and continuations were published in the Federal Register Tuesday, August 21, 2007. As of November 1, 2007, the claims in each application may not exceed 5 independent claims or 25 total claims absent the applicant assisting the examination process through the filing of an Examination Support Document (ESD). The following is taken from the published rules package:

- Applicants may present, without an ESD, up to:

- Five (5) independent claims or
- Twenty-five (25) total claims in an application.
- Applicant may present more than 5/25 claims, if applicant files an ESD before the first Office action on the merits (FAOM).
- The 5/25 claim threshold does not count withdrawn claims.
 - Applicant may provide a suggested restriction requirement (SRR) before first Office action or a restriction requirement.
- The 5/25 claim threshold does count all of the claims present in other copending application(s) having a patentably indistinct claim, but not the claims in issued patents.
 - Applicant may present up to 15/75 claims via an initial application and 2 continuation or CIP applications prosecuted serially.

The final rules will become effective November 1, 2007, and will apply to all pending applications as of that date. Applicants are advised to ensure that the elected claims are compliant with the new rules to avoid delay of prosecution. There will be no change to the examiner practice prior to the date the rules become effective. Information on the new rules will be available at: <http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html>.

If Applicant has any questions concerning the new rules, email patentpractice@uspto.gov or call 571-272-7704.

Ruixiang Li

Ruixiang Li, Ph.D.
Primary Examiner
September 7, 2007

RUIXIANG LI, PH.D.
PRIMARY EXAMINER